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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,434	08/19/2003	Jen Sheen	00786/366003	4423
21559	7590	07/14/2006	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110				IBRAHIM, MEDINA AHMED
		ART UNIT		PAPER NUMBER
		1638		

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/643,434	SHEEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 03 May 2006.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-16 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____ .

## DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 05/03/06 in reply to the Office action of 11/03/05 has been entered. Claims 15 and 16 are added. Therefore, claims 1-16 are pending and are examined.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment and/or upon further consideration.

### ***Claim Rejections - 35 USC § 112***

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a plant transformed with a recombinant nucleic acid encoding the plant MAPKKK polypeptide of SEQ ID NO: 7, 9, 11, 15 or 19, a vector comprising said nucleic acid operably linked to promoter functional in plant cells, does not reasonably provide enablement for a plant transformed with a recombinant nucleic acid encoding any constitutively active MAPKKK including those from animals and fungi and kinase domains thereof including those having substantial identity to SEQ ID NO: 7, 9, 11, 15 or 19. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in the last Office action of 11/03/05. Applicant's arguments filed 05/03/06 have been fully considered but are not deemed persuasive.

Applicant correctly states that a patent application need not repeat what is

already known in the prior art. Applicant cites *Hybritech Inc. v. Monoclonal Antibodies* (fed. Cir. 1986); *In re Wands* (Fed. Cir. 1988); *Spectra-Physics, Inc v. Coherent, Inc* (Fed. Cir. 1987); *In re Marzocchi* (CCPA 1971); and *Paperless Accounting, Inc. v Bay Area Rapid Transit Sys.*, (Fed. Cir. 1986) to support this position. Examiner responds that while a patent need not teach, and preferably omits what is well known in the art, the Federal Circuit has cautioned against over-reliance on the rule, cited by Applicant. In *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), for example, the court states: "[T]hat general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. .... It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

Applicant asserts that the teachings of the instant specification and the level of skill known in the art would allow one to screen plants transformed with different nucleic acids encoding a constitutively active kinase of a MAPKKK or kinase domain thereof using techniques known in the art, without undue experimentation.

These are not found persuasive because Applicant's arguments are not commensurate with the scope of the claims. While one skilled in the art can perform screening transformed plants expressing a nucleic acid encoding MAPKKK by using techniques known in the art, the rejected claims are not drawn to screening transformed plants expressing MAPKKK. The rejected claims are drawn to plants transformed with a

recombinant nucleic acid encoding a constitutively active kinase domain of any MAPKKK including those from animals and fungi and kinase domains thereof. Neither the instant specification nor the prior art provide guidance for how to identify animal and fungi MAPKKKs encoding sequences or kinase domains thereof that are capable of regulating signal transduction pathways upon expression in a transgenic plant. There is no evidence in the record that MAPKKK proteins from animals and fungi will possess similar function in plants as in animals and fungi. In addition, the *Genentech* court (Supra) held that [w]hile every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention". Id. In this case, as in *Genentech*, the specification does not provide the "reasonable detail .....to enable members of the public to understand and carry out the claimed invention", i.e., claims drawn to the use of all animal and fungi kinase domains of MAPKKK for the production of transgenic plants having altered auxin response, seed development or activated stress response.

Applicant alleges that the Office action fails to provide evidence or scientific reasoning to support the rejection. Applicant argues that it is not necessary that every claimed embodiment to be operative, and that a considerable amount of experimentation is permissible if it is routine.

Applicant agrees with Applicant that it is not necessary that every claimed embodiment be operative. However, both the MPEP (see section 2164) and related case law require that the scope of the enabling disclosure be commensurate with the

scope of the claims. The specification enables only for claims limited to transgenic plants expressing the nucleic acids encoding the MAPKKK from Arabidopsis and tobacco (SEQ ID NO: 7, 9, 11, 15 and 19). See, *in re Fischer*, 166 USPQ 19 24 (CCPA 1970) where the court determined that the scope of the claims must bear a reasonable correlation with the scope of the enablement.

With respect to the alleged lack of evidence supporting the rejection, Examiner notes that Applicant's own specification and working examples provide evidence that supports the instant rejection. For example, on page 2, Applicant states "(a)lthough many plant MAPK, MAPKK, and MAPKKK homologues have been identified based on sequence conservation and functional complementation in yeast, their precise physiological functions in plants are largely unknown... It also remains unclear whether and how these homologues constitute specific MAPK kinase cascades". Also, at page 9, the specification states "a kinase domain of MAPKKK is relatively unstable". One would not expect that unstable kinase domain expressed in a transgenic plant would provide stably a transformed plant with predictable phenotype, i.e., altered auxin response or seed development or activated stress response.

The MPEP, section 2164 .01(b), states "(a) key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening." In this application, Applicant has not provided guidance for a representative number of nucleic

acids encoding MAPKKK and kinase domains thereof required for the production of the claimed transgenic plants.

New claims 15 and 16 are included in the rejection because Applicant has not provided guidance for how and where to modify SEQ ID NO: 7, 9, 11, 15, and 19 to produce nucleic acids having substantial identity (as defined on page 6 of the specification) thereof for the production of transgenic plants of the claims.

Therefore, for all the reasons discussed above and in the last Office action, the claimed invention cannot be practiced throughout the broad scope without undue experimentation. Therefore, the rejection is proper.

***Claim Rejections - 35 USC § 102***

Claims 1, 4-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanksley et al (US 5, 648, 599, Applicant's IDS). This rejection is repeated for the reasons of record as set forth in the last Office action of 11/03/05. Applicant's arguments filed 05/03/06 have been considered but are not deemed persuasive.

Applicant reiterates that the *Pto* gene of Tanksley is not a MAPK, a MAPKK or even a MAPKKK, and that it does not encode a polypeptide with a regulatory domain that can be deleted for constitutive activity as in MAPKKK (response, p. 7).

Examiner maintains that the rejection is proper given that the claims do not recite specific structural characteristics such as percent of identity or SEQ ID NO: that would distinguish the activated kinase domain of *pto* from that of the kinase domain of MAPKKK from various natural sources. The serine/threonine kinase domain of the *Pto* polypeptide is activated upon recognition of the invading pathogen gene product.

Therefore, transgenic plants expressing a kinase domain of MAPKKK is indistinguishable from the transgenic plants expressing the serine threonine kinase domain of Tanksley. Therefore, Tanksley et al teaches the claimed invention, as stated in the last Office action.

***Remarks***

Claims 2-3 and 15-16 are free of the prior art of record.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to

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5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7/10/06

Mai

MEDINA A. IBRAHIM  
PRIMARY EXAMINER

